

DMB
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reclassification petitions for medical devices.

DATES: Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reclassification Petitions for Medical Devices—21 CFR 860.123 (OMB Control Number 0910-0138)—Extension

FDA has the responsibility under sections 513(e), 513(f), 514(b), 515(b), and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(e), 360c(f), 360d(b), 360e(b), and 360j(l)) and part 860 (21 CFR part 860), subpart C, to collect data and information contained in reclassification petitions. The reclassification provisions of the act allow any person to petition for reclassification of a device from any one of the three classes (I, II, and III) to another class. The reclassification content regulation (§ 860.123) requires the submission of sufficient, valid scientific evidence demonstrating that the proposed classification will provide a reasonable assurance of safety and effectiveness of the device for its intended use. The reclassification provisions of the act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device. The reclassification petitions requesting classification from class III to class II or class I, if approved, provide an alternative route to the market in lieu of premarket approval for class III devices.

Respondents are device manufacturers seeking reclassification.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
860.123	6	1	6	500	3,000

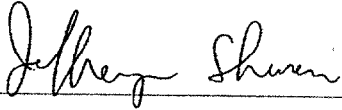
¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on current trends and actual reclassification petitions received, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is

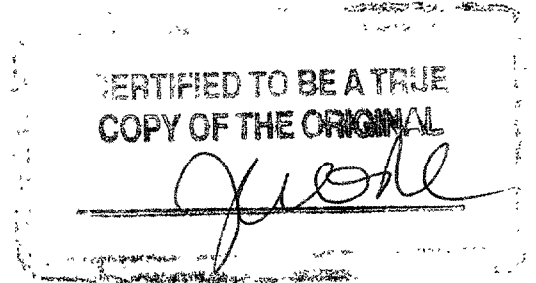
based upon estimates by FDA administrative and technical staff that are familiar with the requirements for submission of a reclassification petition, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Dated: **SEP 07 2005**

September 7, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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